ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

COMPARATIVE CLINICAL EFFICACY OF OIL PREPARED WITH STEM BARK AND FRUIT OF *SHIRISHA* IN THE MANAGEMENT OF *DARUNAKA* (DANDRUFF) - A RANDOMISED, SINGLE BLIND CLINICAL STUDY

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Article info

Article History:
Received: 13-04-2025
Accepted: 05-05-2025
Published: 15-06-2025

KEYWORDS:
Darunaka, Dandruff, *Shirisha phala taila, Shirisha tvak taila*.

ABSTRACT

Darunaka, a *Kshudra Roga* classified under *Kapalagata Roga* in Ayurveda, is a common scalp disorder characterized by *Kandu* (itching), *Kesacyuti* (falling of hair), *Ruksata* (dryness), *Tvaksputana* (scaling/cracking of skin). It primarily arises due to vitiation of *Vata* and *Kapha Doshas*. Despite being non-fatal, it significantly impacts an individual's quality of life and aesthetics. This study aimed to comparative clinical efficacy of oil prepared with stem bark and fruit of *Shirisha* in the management of *Darunaka* (dandruff), assessing its role in *Dosha Samana* (pacification), symptom relief, and overall patient wellness. A clinical study was conducted involving patients diagnosed with cardinal symptoms of *Darunaka*. The trial formulation was administered as external application for 30 days. Classical Ayurvedic diagnostic criteria, as well as modern clinical parameters, were employed for assessment. Pre- and post-treatment observations were documented, focusing on signs such as *Kandu, Kesacyuti, Tvak ruksata,* and *Tvaksputana*. The results indicated a significant reduction in classical signs and symptoms of *Darunaka*. Improvements were noted in scalp health, reduction in itching. The therapy was well-tolerated by all participants, with no adverse effects reported. The study reinforces the efficacy of classical Ayurvedic approaches and suggests further large-scale research to validate these findings and integrate traditional treatments into contemporary scalp care.

INTRODUCTION

Dandruff has a very high rate of incidence and prevalence. Approximately 50% of the general adult population worldwide is affected. Despite not causing mortality, it does have an impact on quality of life.[1] As it has high cosmetic value there will always be an influx of new medicines and therapies to treat dandruff. Therefore, we are working towards the introduction of plant-based drugs to ensure cost efficiency. Present drugs in market such as zinc pyrithione, tar-based shampoos, ketoconazole shampoos, selenium sulphide shampoos are being used.[2] The skin on the scalp gets affected with *Daruṇaka* (cracked) and causes *Kandu* (itching on scalp), *Rūkṣata* (dry), *Keśabhūmiprapaṭyatha* (falling of hair) due to increase of *Kapha vata* together.[3] For not only minimizing the side effects but also to be useful for the management of *Darunaka* after referring various Ayurvedic literatures and *Guna karma Shirisha* is selected for management of *Darunaka* because it contains *Kustaghna, Kandugna* property.[4]

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Quick Response Code

https://doi.org/10.47070/ijapr.v13i5.3669

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AIM AND OBJECTIVES

To comparative clinical efficacy of oil prepared with stem bark and fruit of *Shirisha* in the management of *Darunaka* (dandruff).

MATERIALS AND METHODS

The study was conducted on 40 patients in the OPD of P.G.Department of *Dravyaguna* at S.V.Ayurvedic Hospital, Tirupati. The patients were divided into 2 groups with 20 patients in each group.

Group A: Advised to administer *Shirisha tvak taila* Quantity sufficient depending upon the surface area of the scalp involved daily.

Group B: Advised to administer *Shirisha Phala taila* Quantity sufficient depending upon the surface area of the scalp involved daily.

Study design

Randomized controlled single blind clinical study to comparative clinical efficacy of oil prepared with stem bark and fruit of *Shirisha* in the management of *Darunaka* (dandruff).

Inclusion criteria

1. Patients who have signs and symptoms of *Darunaka* were included in the trial.
2. Age group between 5 years to 70 years and gender were included.

Exclusion criteria

1. Patient having other skin diseases like scalp psoriasis, atopic dermatitis and hypersensitivity.
2. Other chronic conditions of the skin were excluded.

Screening Method

Every subject had their medical history taken, a clinical examination, and laboratory tests, including a *Darunaka* screening, in accordance with the provided research proforma.

Upon registration, each participant's age, gender, marital status, socioeconomic status (rural versus urban), religion, education, occupation, and monthly income, as well as their hunger, digestion tract, addiction, bowel habit, dietary habits, and lifestyle were investigated.

After preliminary registration, detailed case history of the patient was taken and physical examination was done as per following schedule.

Chief Complaints with Duration

- History of present illness
- History of past illness
- Family history of relevant disease
- Physical examination

The following were assessed during the general examination: height, weight, body temperature, pallor, cyanosis, icterus, oedema, thyroid enlargement, lymph nodes, pulse rate, blood pressure, respiration rate, and general condition.

Parameters of Assessments

Criteria to assess the effect of the test drug

All the selected subjects were advised to come for follow up every 15 days up to one month. Assessment of Subjective and Objective parameters was done as per the proforma.

Approval of IEC

Institutional Ethical Committee's approval was taken for the prospective, randomized, single blind, comparative clinical study.

Procurement of drug

Collection of Drug

Albizia lebbeck plant is identified from natural sources based on its morphological characters then matured plant is selected to collect the stem bark and Pods were collected at fruiting season i.e., December at Atreya Vanam, S. V. Ayurvedic college, Tirupati.

Stem bark scrubbed with cloth to remove debris and dirt. Pods were rinsed with clean water.

Preparation of *Shirisha tvak taila*

A decoction is made by boiling *Shirisha* bark with water, and this is combined with *Tila taila* and *Shirisha* bark *Kalka*. when the mixture is heated over *Mandagni Taila paka lakshanas* were observed. Following proper preparation, the oil is filtered and transferred to bottles for storage.

Preparation of *Shirisha Phala taila*

In order to make *Shirisha phala taila*, one kilogram of *Phala kalka* was ground, combined with sixteen liters of water and four litres of *Tila taila,* and then brought to a boil over low heat. Following the observation of *Taila paka lakshanas*, the oil was allowed to cool before being filtered through muslin cloth and preserved in dry, clean bottles.

Assessment parameter patients were contacted by phone to confirm that they were taking the medication on a regular basis. The study excluded patients who were not taking the medication on a regular basis.

Criteria to assess the effect of the test drug

It was recommended that all of the chosen subjects attend follow-up appointments every 15 days for a total of 30 days. In order to evaluate the many factors contributing to the condition, demographic information was gathered from each of the 40 patients and displayed in the findings section.

Subjective parameters of assessment[5]

Subjective parameters	Assessment	Score
Kandu (Itching)	No itching	0
	Mild (doesn't disturbs daily routine)	1
	Moderate (frequently, tolerable, disturbs daily routine)	2
	Severe (constantly, intolerable, disturbs daily routine)	3
Kesacyuti (Falling of hair)	1 to 5 hairs fall on combing/washing	0
	Mild (less than 20 hair falls on combing/washing)	1
	Moderate (more than 20 hair falls on combing/washing)	2

	Severe (less than 20 hair falls on simple hand strength	3
Ruksata (Dryness)	No dryness	0
	Mild- Dryness with rough skin	1
	Moderate- Dryness with scaling	2
	Severe- Dryness with cracking skin	3
Tvaksputana (Scaling/ Cracking of skin)	No scaling	0
	Mild-Scraping presented	1
	Moderate- Scaling visible over hair	2
	Severe- Scaling visible over hair with oozing of blood	3

Objective parameters of assessment[6]

Objective parameters	Assessment	Score
Erythema	No erythema	0
	Faint pink colour	1
	Pink colour	2
	Red colour	3
Dandruff	No dandruff	0
	Only scraped	1
	Obvious scaling	2
	Obvious sheets	3
Lesion Extended	No lesion	0
	1%- 30% scalp area	1
	31%- 70% scalp area	2
	71%- 100% scalp area	3

Criteria for assessment of the results

S.No.	Interpretation of effect	Definition	Result of drug in Percentage
1	Complete remission	No visible dandruff, no itching, no scalp flaking, and no associated irritation. The scalp appears completely healthy.	100%
2	Markedly improved	Significant reduction in dandruff flakes, itching, and irritation. Mild residual symptoms may still be present but do not cause discomfort.	76% to 99 %
3	Moderately improved	Noticeable reduction in dandruff symptoms, but flaking and mild irritation persist. The scalp condition has improved, but some discomfort remains.	51% to 75%
4	Mildly improved	Slight reduction in dandruff symptoms, but visible flakes, itching, and irritation are still present. Treatment has had a minor impact.	26% to 50%
5	Unchanged	Little to no relief from dandruff symptoms. The condition remains largely the same, with persistent flakes, itching, and irritation.	Below 25%

Statistical evaluation Microsoft Excel was used to record all of the values derived from the subjective and objective criteria, and master tables were created. GraphPad Prism Quick Calculations, an online program, was used to evaluate the obtained values for statistical parameters such as mean, SD, SE, t value, and p value. The findings are displayed.

OBSERVATIONS AND RESULTS

Based on Demographic Data

Age: Maximum subjects 16 (40%) were of the age group of 26 to 35 years, 9 subjects (22.5%) were in the age group between 16 to 25 years, 9 subjects (22.5%) were in the age group between 36 to 45 years, 4 subjects (10%) were in the age group between 5 to 15 years and 2 subjects (5%) were in the age group between 46 to 55 years. Frequently *Darunaka* can affects the population of adolescents, young adults and senior adults. The statistics of this also proves the same.

Gender: Among 40 subjects selected for the study, maximum subjects 21 (52.5%) were of male gender, 19 subjects (47.5%) were female gender. Nothing specific can be drawn from this observation as this could be due to the demographic facts or due to small sample.

Region: Among 40 subjects selected for the study, maximum subjects 28 (70%) were from urban region, 12 subjects (30%) were rural region. Nothing specific can be drawn from this observation as this could be due to the demographic facts or due to small sample.

Marital status: Among 40 Subjects selected for the study, maximum subjects 23 (57.5%) were married, 17 subjects (42.5%) were unmarried. This might be due to stress in post marital life as *Manasatapa* is one of the causative factors for *Darunaka*.

Education: Among 40 subjects selected for the study, maximum subjects 29 (72.5%) were attained college, 5 Subjects (12.5%) can read and write, 4 subjects (10%) attained school, 2 subjects (5%) were Illiterate. Nothing specific can be drawn from this observation as this could be due to the demographic facts or due to small sample.

Socioeconomic status: Among 40 Subjects selected for the study, maximum subjects 31 (77.5%) were from middle class socioeconomic status, 5 subjects (12.5%) were from upper class, 4 subjects (10%) poor socioeconomic status. Nothing specific can be drawn from this observation as this could be due to the demographic facts or due to small sample.

Occupation: Among 40 subjects selected for the study, maximum subjects 16 (40%) were students, 10 subjects (25%) were employees, 9 subjects (22.5%) were housewives, 3 subjects (7.5%) farmers, 2 subjects (5%) were in business. Student are mostly under the age group of adolescents, stress factor, compact activities of daily life may lead to the ignorance of proper hair care.

Religion: Among 40 subjects selected for the study, maximum subjects 31 (77.5%) were Hindu, 5 subjects (12.5%) were Muslim, 4 subjects (10%) were Christian. This may be due to the dominance of Hindu population in the study site.

Family history: Among 40 subjects selected for the study, maximum subjects 29 (72.5%) had family history, 11 subjects (27.5%) were with no family history. Family inheritance (*Dosa bija*) affects skin barrier function, scalp oil production, and immune response, making some individuals more susceptible.

Diet: Among 40 subjects selected for the study, maximum subjects 37 (92.5%) were mixed diet, 3 subjects (7.5%) were vegetarian. *Guru ahara* and *Amla ahara atisevana nidana* can result in *Darunaka*.

Bowel habit: Among 40 subjects selected for the study, maximum subjects 29 (72.5%) were with regular bowel habits, 11 Subjects (27.5%) had constipation. Even though studies have shown that people with constipation have more tendency for *Darunaka*, in my study due to less sample size it is insignificant.

Sleep pattern: Among 40 subjects selected for the study, maximum subjects 24 (60%) were with disturbed sleep, 13 subjects (32.5%) were adequate sleep, 3 subjects (7.5%) were with excessive sleep. *Diva Svapna* and *Jagarana* play a significant role in the pathogenesis of *Darunaka* by disturbing *Vata* and *Kapha Prakopa*.

Deha prakrti: Among 40 subjects selected for the study, maximum subjects 18 (45%) were *Vata-Pitta*, 8 subjects (20%) were *Vata-Kapha*, 7 subjects (17.5%) were with *Pitta-Kapha*, 3 subjects (7.5%) were *Vata*, 3 subjects (7.5%) were *Pitta*, 1 subject (2.5%) were *Kapha*, 0 subjects (0%) were *Vata-Pitta-Kapha*. *Vata-Pitta prakrti* individuals are most likely susceptible to *Darunaka* due to their inherent *Ruksa, Khara, Usna* and *Tiksna gunas*.

Sara: Among 40 Subjects selected for the study, maximum subjects 11 (27.5%) were *Raktha Sara*, 8 Subjects (20%) were *Asthi Sara*, 7 Subjects (17.5%) were with *Majja*, 7 Subjects (17.5%) were with *Tvak*, 6 Subjects (15%) were *Mamsa*, 1 Subjects (2.5%) were *Medho*, 0 Subjects (0%) were *Sukra*.

***Nidana*:** Among 40 subjects selected for the study, maximum subjects 11 (27.5%) were *Ahara-vihara*, 9 subjects (22.5%) were *Ahara-vihara-Manasika*, 7 subjects (17.5%) were *Vihara*.

Kesa varna: Among 40 subjects selected for the study, maximum subjects 21 (52.5%) were *Syava*, 10 subjects (25%) were *Pita*, 9 subjects (22.5%) were *Palitya*, 0 subjects (0%) were *Sveta*.

Kesa akrti: Among 40 subjects selected for the study, maximum subjects 23 (57.5%) were straight, 14 subjects (35%) were wavy, 9 subjects (22.5%) were curly.

***Kesa svabhava*:** Among 40 subjects selected for the study, maximum subjects 22 (57.5%) were *Mrudu*, 18 subjects (45 %) were *Ruksa*.

***Kesasuchi*:** Among 40 subjects selected for the study, maximum subjects 27 (67.5%) were using shampoo, 7 subjects (35%) were using soap nut, 6 subjects (15%) were using medicated shampoo.

***Taila*:** Among 40 subjects selected for the study, maximum subjects 24 (60%) were using coconut oil, 9 subjects (22.5 %) were using any kind of oil (nothing), 5 subjects (12.5%) were using *Eranda taila*, 2 Subjects (12.5%) were using *Tila taila*.

RESULTS

Effect of therapies on subjective parameters in the subjects of Group A

Parameter	N	BT	AT	Mean Difference	Relief %	SD		S.E	't'	'p'	Inference
		Mean	Mean			BT	AT				
Kandu	20	1.65	1.10	0.55	33.3%	0.88	0.79	0.153	3.5838	0.0020	Statistically very significant
kesacyuti	20	0.90	0.85	0.05	5.5%	0.85	0.75	0.050	1.0000	0.3299	Statistically not significant
Ruksata	20	1.55	1.05	0.50	32.2%	0.51	0.60	0.136	3.6839	0.0016	Statistically very significant
Tvaksputana	20	1.70	1.35	0.35	20.5%	0.47	0.59	0.131	2.6659	0.0153	Statistically significant

From above data it can be inferred that *Kandu, Ruksata*, statistically very significant, *Tvaksputana* is statistically significant whereas *Kesacyuti* statistically not significant.

Effect of therapies on subjective parameters in the subjects of Group B

Parameter	N	BT	AT	Mean Difference	Relief %	SD		S.E	't'	'p'	Inference
		Mean	Mean			BT	AT				
Kandu	20	1.95	0.10	1.85	94.8%	0.69	0.45	0.182	10.1799	0.0001	Statistically extremely significant
Kesacyuti	20	0.90	0.65	0.25	27.7%	0.79	0.67	0.099	2.5166	0.0210	Statistically significant
Ruksata	20	1.55	0.15	1.40	90.3%	0.69	0.37	0.197	7.0940	0.0001	Statistically extremely significant
Tvaksputana	20	1.60	0.35	1.25	78.1%	0.50	0.67	0.160	7.8037	0.0001	Statistically extremely significant

From above data it can be inferred that *Kandu, Ruksata, Tvaksputana* is statistically extremely significant whereas *Kesacyuti* statistically significant.

Effect of therapies on objective parameters in the subjects of Group A

Parameter	N	BT	AT	Mean Difference	Relief %	SD		S.E	't'	'p'	Inference
		Mean	Mean			BT	AT				
Erythema	20	0	0	0	0%	0	0	0	0	0	-
Dandruff	20	1.70	1.40	0.30	17.64%	0.47	0.60	0.128	2.3486	0.0298	Statistically significant
Lesion extended	20	2.10	1.95	0.15	7.14%	0.85	0.94	0.150	1.0000	0.3299	Not statistically significant

*Note- In group A no subjects have presented with erythema

From above data it can be inferred that dandruff, lesion extended is statistically significant whereas lesion extended not statistically significant.

Effect of therapies on objective parameters in the subjects of Group B

Parameter	N	BT	AT	Mean Difference	Relief %	SD		S.E	't'	'p'	Inference
		Mean	Mean			BT	AT				
Erythema	20	0.15	0.00	0.15	100%	0.37	0.00	0.082	1.8311	0.0828	Statistically insignificant
Dandruff	20	1.75	0.40	1.35	77%	0.44	0.68	0.167	8.1021	0.0001	Statistically extremely significant
Lesion extended	20	2.25	0.65	1.60	71.1%	0.79	1.09	0.255	6.2631	0.0001	Statistically extremely significant

From above data it can be inferred that dandruff, lesion extended is statistically extremely significant whereas erythema statistically insignificant.

Comparison of overall effects of therapies in 40 subjects of *Darunaka* in Group A & Group B

S.No	Status	Group A	Group B
1	Complete relief	0%	15%
2	Marked improvement	5 %	50%
3	Moderate improvement	0%	15%
4	Mild improvement	25%	15%
5	No improvement	70%	5%

The final outcome can be calculated as the proportion of benefits in terms of subjective and objective outcomes being improved, Above data clearly shows that Group A & Group B gave p value (<0.0001). Group-A clinical study there was 0 (0 %) was noted complete relief, 1 (5%) were markedly improved, 0 (0%) were moderate improvement, 5 (25%) mildly improved, 14 (70%) shows no improvement. It was observed that in the where as in the Group- B clinical study there was 3 (15%) was noted complete relief, 10 (50%) were markedly improved, 3 (15%) were moderate improvement, 3 (15%) mildly improved, 1 (5%) shows no improvement.

DISCUSSION

There are many available references of *Shirisha* (*Albizia lebbeck* Benth.) in Ayurvedic literature, pointing to the use of bark and not the other parts. So other part (i.e., fruit) is being studied.

This is easily available drug and there is no work has been done on this point of perspective of *Shirisha* in *Darunaka*. Mode of action based on *Shirisha rasas* in *Darunaka.*

Tikta rasa reduces *Kapha* and *Pitta* which detoxifies the skin, reduces inflammation and itching, controls microbial growth.

Kasaya rasa reduces *Kapha* and *Pitta* contracts tissues, reducing excessive sebum secretion, aids wound healing and prevents further scalp damage.

Madhura balances *Vata* and *Pitta*, slightly increases *kapha* nourishes and moisturizes the scalp, promotes healthy hair growth, reduces excessive dryness and irritation.

Katu reduces *Kapha* and *Vata* increases circulation and removes toxins acts as a scalp stimulant.

Laghu guna sodhana due to its quick penetrating property, promotes *Kapha-kledaka sosana* excess moisture and reducing the excessive sebum accumulation on the scalp.

Darunaka is a *Kapha-vata* predominant condition, worsened by extremes of heat or cold. *Anusna virya* maintenance moderation.

Glycosides present in *Shirisha phala* contribute to anti-dandruff and anti-inflammatory properties. They exhibit antifungal activity, effectively inhibiting malassezia, the fungus associated with dandruff. Certain glycosides also possess keratolytic action, helping in the exfoliation of dead scalp cells, thereby reducing scaling and flaking.[7] They modulate cyclooxygenase (COX) and lipoxygenase (LOX) enzymes, thereby reducing inflammation and itching (*Kandu*).[8]

Tannins from *Shirisha phala* play a crucial role in dandruff prevention and scalp health. They possess *Kasaya* which help reduce excessive sebum production, controlling *Kapha dosa* aggravation responsible for oily dandruff. Tannins exhibit strong antifungal and

antibacterial activity, preventing microbial overgrowth that exacerbates *Darunaka*. Their antioxidant properties protect the scalp from oxidative stress further reducing inflammation and irritation (*Usnata, Daha*).[9]

CONCLUSION

The randomized clinical trial demonstrated that *Shirisha phala taila* (fruit-based oil) provided significantly greater relief than *Shirisha tvak taila* (bark-based oil). Patients using the fruit-based oil experienced a marked reduction in itching, dryness, dandruff flakes, and scalp lesions with a 65% complete relief rate compared to only 5% in the bark-based group. The observed improvements support the Ayurvedic understanding of *Shirisha's* therapeutic properties and align with modern phytochemical insights into its antifungal and scalp-conditioning effects.

While the study provides promising evidence for the use of *Albizia lebbeck* in dandruff treatment, further research with larger sample sizes and extended follow-up periods is needed to assess long-term efficacy and recurrence rates.

Acknowledgment

This study was conducted in S. V. Ayurvedic Hospital, Tirupati, Andhra Pradesh, India.

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Cite this article as:
E. Rachana, S. Pavan Kumar, K.C. Ragamala. Comparative Clinical Efficacy of Oil Prepared with Stem Bark and Fruit of Shirisha in the Management of Darunaka (Dandruff) - A Randomised, Single Blind Clinical Study. International Journal of Ayurveda and Pharma Research. 2025;13(5):1-7.
https://doi.org/10.47070/ijapr.v13i5.3669
Source of support: Nil, Conflict of interest: None Declared

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